DEPARTMENT OF HEALTH HUMAN SERVICES

Public Health Service

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MAY 23 2001

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Arve Johan Andressen
Managing Director, President and
Chief Executive Officer
Laerdal Medical AS
P.O. Box 377
Tanke, Svelands Gt. 30
N-4001, Stavanger, Norway

Dear Mr. Andressen:

During an inspection of your firm located in Stavanger, Norway on February 5 through February 8, 2001, our investigator determined that your firm manufactures suction pumps, suction units, Laerdal suction units, face shields, pocket masks, resuscitators and other basic life support equipment. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below.

1. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and are held in quarantine or otherwise adequately controlled until released, and not releasing the devices for distribution until the activities required in the Device Master Record (DMR) are completed, as required by 21 CFR 820.80(d). For example:

   a. The Laerdal inspector failed to identify discrepancies in the final testing of the Laerdal Suction Unit (LSU) prior to release of the devices for distribution.

   b. There were [redacted] LSU units shipped without the required labeling including the device part number.

2. Failure to establish and maintain adequate procedures for receiving, review, and evaluation of complaints by a formally designated unit ensuring that all complaints are processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1). For example, 22 LSU complaints for the period May 31, 2000, through February 2, 2001, revealed that

5 complaints were still open. The specified timeframe in the procedures for closing complaints is 30 days.

3. Failure to establish and maintain adequate procedures for implementing corrective and preventive action including requirements for investigating the cause of nonconformities relating to product, processes, and the quality system, and submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review, as required by 21 CFR 820.100(a)(2) and (7). For example:

   a. There is a Nonconformance Report (NCR) procedure. However, a review of the NCR's for the LSU from September 26, 2000, through November 2000, revealed that adequate investigations did not occur in order to implement appropriate corrective and preventive actions. Three out of 8 NCR's remain unresolved. NCR 572, dated November 20, 2000, stated there was not enough power being generated by the device; NCR 706, dated December 13, 2000, stated there was no light emitting diode (LED) light; and NCR 674, dated September 26, 2000, stated the LSU battery was not working.

   b. Management did not review the NCR's, corrective and preventive action, and cause of the problem.

4. Failure to establish and maintain adequate procedures that define the responsibility for review and the authority for the disposition of nonconforming product, setting forth the review and disposition process, documenting the disposition of nonconforming product, and the signature of the individual(s) authorizing the disposition, as required by 21 CFR 820.90(b)(1). For example, review of your NCR's for the LSU from September 26, 2000, through November 2000 shows that 3 out of [redacted] of the reports are unresolved. The NCR is sent to production for review, assessment, and investigation. Following production's assessment, the investigation is documented on complaint form F1601, and the NCR is filed in the complaint record. Although the procedures identify a responsible person to review, followup and close the NCR, this had not been done. Upon questioning, Laerdal had no explanation for the lack of final review and closure.

5. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example, the labeling design of the LSU was changed to include the device part number on each unit.

Design validation and verification was not performed prior to approval of the labeling. The new labeling went to production and was molded into the connector of each unit.

6. Failure to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, and to document the training, as required by 21 CFR 820.25(b). For example, no training for personnel for 1999 through 2000 was documented as having been provided.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Given the serious nature of these violations of the Act, all devices manufactured by Laerdal Medical AS, P.O. Box 377, Tanke Svelands Gt. 30, N-4001, Stavanger, Norway may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, we will request an establishment re-inspection at that time. As soon as the re-inspection has taken place, the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your devices may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance,

Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Cc:
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